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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,871	SEGAL ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/19/03, 2/27/04, 5/07/04 +7/05/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) *28-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27,67 and 68* is/are rejected.

7)☒ Claim(s) *1-27 and 67-68* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/27/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

LD

DETAILED ACTION

Election/Restrictions

1. Applicant's election of:

a composition comprising a fusion polypeptide, wherein said fusion polypeptide comprising a first amino acid sequence which can bind to a carbohydrate and a second amino acid sequence comprising a ligand for a cell surface polypeptide; wherein the elected antigen bearing target is a mammalian cell, the ligand is a ligand for a cytokine receptor, wherein the cytokine is GM-CSF; the elected carbohydrate binding domain is sialic acid.

in the reply filed on 07/05/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

However, in response to Applicant's request to withdraw the restriction requirement to a hemagglutinin species, the request is granted. The Office withdraws the restriction requirement to a hemagglutinin species.

2. Additionally, Applicant is reminded that the restriction requirement issued 02/17/2005 is a restriction among multiple patentably distinct inventions, not an election of species.

Status of Claims

3. Claims 1-68 are pending. Claims 28-66 are withdrawn from examination because the claims are directed to a non-elected invention. Claims 1-27 and 67-68 are under examination.

Specification

4. The abstract of the disclosure is objected to because the disclosure provides two different abstracts. It is not readily apparent if the abstract provided on page 201 or page 976 of the disclosure is the preferred abstract for the claimed invention. Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: The term "effector" is misspelled as "effeector" in last sentence, last paragraph, page 1 of the disclosure. Appropriate correction is required.

Claim Objections

6. Claims 1-27 and 67-68 are objected to because of the following informalities: the recitation "a second amino acid sequence comprising a ligand for a cell surface polypeptide" is objected. In the instant, the recitation is awkwardly presented. It is believed that the intended meaning of the recitation is "a second amino acid sequence comprising the amino acid sequence of a ligand for a cell surface polypeptide of a leukocyte". However, as presented, the recitation does not immediately transmit such intention.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 6-14, 23 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "at least about" in renders the claim indefinite. It is unclear as to what range of specific activity is covered by the term "about" in the recitation "at least about". For the purpose of a prior art search, the cited recitation is substituted with the recitation "at least".

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 23 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant rejection is targeted at the limitation recited in the cited claims.

The claims require the second amino acid sequence having at least five contiguous amino acids of a naturally occurring cytokine, specifically GM-CSF.

It is recognized from teachings that are primarily provided in the specification and the art that the cytokine is the active component that provides the adjuvant activity.

Thus, the claim is drawn encompass second amino acid sequence having at least five contiguous amino acids of a naturally occurring GM-CSF, and function as an

adjuvant. In the instant, the requirement is directed at a genus of polypeptides that is defined only by sequence identity and a function.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient description of a representative number of species by i) actual reduction to practice, ii) reduction to drawings, or iii) disclosure of relevant identifying characteristics. Examples of factors to be considered for the latter requirement include:

- disclosure of complete or partial structure,
- physical and/or chemical properties,
- functional characteristics,
- correlation between structure and function, and
- methods of making.

Each of the listed criteria is addressed in turn below.

i) sufficient description of a representative number of species by actual reduction to practice:

In the instant, the specification only teaches of the full GM-CSF polypeptide. The specification does not teach of a single amino acid sequence that is less that full GM-CSF polypeptide. Ergo, the specification does not provide for sufficient number of species by actual reduction to practice.

ii) sufficient description of a representative number of species by reduction to drawings: The specification does not contain any drawings. Thus, there is insufficient description of a representative number of species by reduction to drawings.

iii) sufficient description of a representative number of species by disclosure of relevant identifying characteristics:

- disclosure of complete or partial structure: While the complete structure of the naturally occurring GM-CSF polypeptide is not provided in the specification, a complete structure of the polypeptide can be readily ascertain from the art. However, no partial structures of the GM-CSF polypeptide are provided in the specification, not to mention those that can be use as an adjuvant.
- physical and/or chemical properties: The only two physical and/or chemical properties that are provided in the specification is that the second amino acid is required to have at least 5 contiguous amino acids of GM-CSF.
- functional characteristics: From the disclosure and the art, it is gathered that the second amino acid sequence is the active component that provides the adjuvant activity.
- correlation between structure and function: The specification does not provide a correlation between the required or expected functional characteristic and the structure that is responsible for the required or expected functional characteristic.
- methods of making the product: Beside the complete GM-CSF polypeptide, the specification does not disclose of method of making any second amino acid sequences that comprises at least 5

contiguous amino acid sequences of GM-CSF, not to mention those that can be use as an adjuvant.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the chemical structure of the second amino acid sequence that is used as an adjuvant in the claimed invention, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of making the second amino acid sequence. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only the complete sequence of GM-CSF, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-2, 4-8, 15-16 and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramshaw et al.[1]

The claims are directed to a composition encoding a fusion polypeptide comprising a first amino acid sequence that can bind to a carbohydrate binding domain, specifically a sialic acid domain, and a second amino acid sequence that is a ligand for a cell surface polypeptide, particularly a cytokine receptor.

The claims require: i) the first amino acid sequence be N-terminal to the second amino acid sequence; ii) the sialic acid comprises at least one of the following carbohydrate structure: N-acetylneuraminic acid, alpha-NeuNAc-[2->6]-Gal, alpha-NeuNAc-[2->6]-GalNAc, alpha-NeuNAc-[2->3]-Gal; iii) the first amino acid comprises a) a carbohydrate-binding domain of a naturally occurring lectin, b) at least 10 contiguous amino acids of a hemagglutinin, wherein the hemagglutinin is defined as an influenza virus hemagglutinin and are contiguous amino acids of an influenza hemagglutinin HA1 domain; iv) the ligand for a cell surface polypeptide is the ligand for a mammalian, particularly mouse, cell surface polypeptide; and v) the ligand for a cell surface

[1] Ramshaw et al. U.S. Patent No. 5866131.

polypeptide is a ligand for a cell surface polypeptide of a) a leukocyte, b) an antigen presenting cell, c) a professional antigen presenting cell, and c) a dendritic cell.

Ramshaw et al. teaches a composition encoding a fusion polypeptide comprising a first amino acid sequence that can bind to a carbohydrate binding domain, and a second amino acid sequence that is a ligand for a cell surface polypeptide, particularly a cytokine receptor. [Figure 6]

The first amino acid sequence of Ramshaw et al. is the hemagglutinin protein. The hemagglutinin protein is a lectin and is an influenza virus hemagglutinin. Since the protein is a lectin, it would a carbohydrate-binding domain of a naturally occurring lectin necessarily have a naturally occurring lectin, specifically sialic acid. Sialic acid has at the following carbohydrate structure: N-acetylneuraminic acid. Furthermore, since the hemagglutinin protein are known to have an HA1 and an HA2 domain, the hemagglutinin protein of Ramshaw et al. necessarily have an HA1 domain. Moreover, since the first amino acid sequence of Ramshaw et al. is the hemagglutinin protein, the first amino acid of used by Ramshaw would necessarily have at least 10 contiguous amino acids of a hemagglutinin. [Example 2, 10, and 12]

The second amino acid sequence of Ramshaw et al. includes the murine interleukin-2 protein, murine tumor necrosis factor protein, and murine interleukin-5 protein. The proteins used by Ramshaw et al. are ligands for cytokine receptors, i.e., interleukin-2 receptor, tumor necrosis factor receptor, and interleukin-5 receptor. These receptors are cell surface polypeptides of leukocyte, an antigen presenting cell, a professional antigen presenting cell, particularly dendritic cell. And since the proteins

used by Ramshaw are murine proteins, the ligand for a cell surface polypeptide is the ligand for a mammalian, particularly mouse, cell surface polypeptide.

In the instant, Ramshaw et al. teaches the claimed composition fusion protein. Ergo, Ramshaw et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramshaw et al., as applied to claim 1, in further view of Meyers et al.[2]

The claim requires the first amino acid sequence be C-terminal to the second amino acid sequence.

The significance of Ramshaw et al. as it pertains to claim 1 is provided above.

Ramshaw et al. does not teach the structural orientation of the amino acid sequences as claimed.

As stated above, the fusion polypeptide of Ramshaw et al. has the following structural order: the first amino acid sequence is N-terminal to the second amino acid sequence. [Figure 6]

However, the art recognizes that a fusion polypeptide having the structural order: the first amino acid sequence is C-terminal to the second amino acid sequence as an

equivalent alternative to a fusion polypeptide having the reverse structural order, as evidenced by Meyers et al. [Lines 40-67, column 22] Hence, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made use a fusion polypeptide having the reverse structural order as that provided by Ramshaw et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because both fusion polypeptides are recognized in the art as equivalent substitutes for one another.

Thus, absent unexpected results to the contrary, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention.

15. Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramshaw et al., as applied to claims 1 and 6-8, in further view of Fiers et al.[3]

The claims require the influenza virus to influenza A virus, a subtype that infects humans, the H1 subtype, strain A/PR/8/34, the H2 or H3 subtype, and any subtype that does not infect humans.

The significance of Ramshaw et al. as it pertains to claims 1 and 6-8 is provided above.

In the instant, it is not readily apparent which influenza strain or subtype the hemagglutinin used Ramshaw et al. is derived.

However, the hemagglutinin protein represent one of the most important viral target structures for the host immune system. The hemagglutinin protein induces

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[2] Meyers et al. U.S Patent No. 6911317.

antibodies that neutralizes the viral infectivity, as evidenced by the teaching provided by Fiers et al. [Paragraph 007]

Hence, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use the hemagglutinin protein of any of the to influenza subtype and strains. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to neutralize viral infectivity. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because it is well known in the art that hemagglutinin protein induces antibodies that neutralize viral infectivity.

Thus, absent unexpected results to the contrary, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention.

16. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramshaw et al., as applied to claims 1 and 15.

The claim requires the ligand for a cell surface polypeptide be a ligand for a human cell surface polypeptide.

The significance of Ramshaw et al. as it pertains to claims 1 and 15 is provided above.

As provided above, Ramshaw et al. teaches the fusion of a first amino acid to a ligand for a murine cell surface polypeptide.

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[3] Fiers et al. U.S PreGrant Pub No. 20030129197.

Ramshaw et al. does not teach the fusion of a first amino acid to a ligand for a human cell surface polypeptide.

However, Ramshaw et al. does suggest the use of a ligand for a human cell surface polypeptide. [lines 63-65 of column 3; lines 12-15, 27-28 and 35-36 of column 4]

Ergo, it would have been prima facie obvious for one of ordinary skill in the art to use a ligand for a human cell surface polypeptide. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to direct the fusion polypeptide to a human cell. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the ligands provided by Ramshaw et al. are ligands for a human cell surface polypeptide

Thus, absent unexpected results to the contrary, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention.

17. Claims 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramshaw et al., as applied to claim 1, in view of Wortham et al.[4]

The claims require the ligand for a cell surface polypeptide be a ligand for a mouse GM-CSF receptor; a ligand having at least 5 contiguous amino acids of a mouse GM-CSF; a ligand that comprises the mouse GM-CSF protein; a ligand for a human

[4] Wortham et al. Enhanced protective antibody responses to PspA after intranasal or subcutaneous injections of PspA genetically fused to granulocyte-macrophage colony-stimulating factor or interleukin-2. Infection and Immunity, 1998, Vol. 66, No. 4, 1513-1520.

GM-CSF receptor; a ligand having at least 5 contiguous amino acids of a human GM-CSF; and a ligand comprises the human GM-CSF protein.

The significance of Ramshaw et al. as it pertains to claims 1 is provided above.

As provided above, Ramshaw et al. teaches the fusion of a first amino acid to a ligand for a murine cell surface polypeptide, particularly murine interleukin-2, murine tumor necrosis factor, and interleukin-5.

However, the use of cytokines as agents to enhance both humoral and cell-mediated responses has been recognized in the art. The art teaches the use of cytokines, specifically, GM-CSF and interleukin-2 to enhance the humoral and cell-meditated immune responses, as evidenced by Wortham et al. [Page 1513]

Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use GM-CSF as the equivalent substitute for interleukin-2. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to enhance the humoral and cell-meditated immune responses. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the GM-CSF is recognized in the art as a functional equivalent for interleukin-2 because both have the ability to enhance the humoral and cell-meditated immune responses.

Furthermore, it would have been prima facie obvious for one of ordinary skill in the art to use either a human or mouse GM-CSF. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to direct the fusion polypeptide to a corresponding human or mouse cell. One of ordinary skill in the art at

the time the invention was made would have had a reasonable expectation of success for doing so because GM-CSF is a ligand for a cell surface polypeptide.

Thus, absent unexpected results to the contrary, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention.

18. Claims 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramshaw et al., as applied to claim 1, in view of Natesan.[5]

The claims require the fusion polypeptide to further comprise a linker interposed between said first and second amino acid sequences, wherein the linker has the formula (GlyxSer)n, wherein n is an integer between 1-15 and x is an integer between 1-10.

The significance of Ramshaw et al. as it pertains to claims 1 is provided above.

Ramshaw et al. teaches a fusion polypeptide. The fusion polypeptide of Ramshaw et al. does not include a linker interposed between said first and second amino acid sequences.

However, the use of linkers can facilitate enhanced flexibility of the fusion protein, reduce steric hindrance between any two fragments of the fusion protein, and facilitate the appropriate folding of each fragment, as evidenced by Natesan et al. Natesan et al. also provide examples of linkers that can be used, such as (Gly4Ser)3. [Lines 40-64, column 28] Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use (Gly4Ser)3 interposed between said first

[5] Natesan. U.S Patent No: 6015709.

and second amino acid sequences. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to enhanced flexibility of the fusion protein, reduce steric hindrance between any two fragments of the fusion protein, and facilitate the appropriate folding of each fragment. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because linkers facilitate enhanced flexibility of the fusion protein, reduce steric hindrance between any two fragments of the fusion protein, and facilitate the appropriate folding of each fragment.

Furthermore, it would have been prima facie obvious for one of ordinary skill in the art to use either a human or mouse GM-CSF. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to direct the fusion polypeptide to a corresponding human or mouse cell. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because GM-CSF is a ligand for a cell surface polypeptide.

Thus, absent unexpected results to the contrary, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 1-27 and 67-68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/666833.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The broadest claim presented for the conflicting patent application is claim 1 Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which

can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The difference between the two claims is that claim 1 of the conflicting patent application requires the presence of an antigen bearing target, whereas claim 1 of the instant patent application does not require the presence of an antigen bearing target. However, claim 1 of the instant patent application is open to the addition of other ingredients, note the transitional language used, "comprising".

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

21. Claims 1-27 and 67-68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/666886.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a vaccine composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The difference between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and "carbohydrate binding domain".

However, a carbohydrate binding domain is encompassed by the generic recitation "first amino acid sequence comprising a cell-surface binding moiety".

The difference between the two claims is that claim 1 of the conflicting patent application requires the presence of a cell, whereas claim 1 of the instant patent application does not require the presence of a cell. However, claim 1 of the instant patent application is open to the addition of other ingredients, note the transitional language used, "comprising".

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented:

22. Claims 1-27 and 67-68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10/667193, in view of Wortham et al.[6]

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The difference between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and "carbohydrate binding domain".

However, a carbohydrate binding domain is encompassed by the generic recitation "first amino acid sequence comprising a cell-surface binding moiety".

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two claims is that claim 1 of the conflicting patent application requires the presence of a cell, whereas claim 1 of the instant patent application does not require the presence of a cell. However, claim 1 of the instant patent application is open to the addition of other ingredients, note the transitional language used, "comprising".

The last difference noted between the two is that claim 1 of the instant patent application is directed at a fusion polypeptide that is administered in claim 1 of the conflicting patent application.

However, it would have been prima facie obvious for one of ordinary skill in the art to administer the polypeptide to a subject because the art teaches that the administration of a cytokine construct enhance humoral as well as cell-mediated responses. [page 1513 of Wortham et al.]

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[6] Wortham et al. Enhanced protective antibody responses to PspA after intranasal or subcutaneous injections of PspA genetically fused to granulocyte-macrophage colony-stimulating factor or interleukin-2. Infection and Immunity, 1998, Vol. 66, No. 4, 1513-1520.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

23. Claims 1-27 and 67-68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-78 of copending Application No. 10/645000.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The broadest claim presented for the conflicting patent application is claim 1. The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide.

The difference between the two claims is that claim 1 of the conflicting patent application requires the presence of an antigen bearing target, whereas claim 1 of the instant patent application does not require the presence of an antigen bearing target. However, claim 1 of the instant patent application is open to the addition of other ingredients, note the transitional language used, "comprising".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claims 1-27 and 67-68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/224661.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a lectin that is capable of binding a carbohydrate and includes the HA carbohydrate binding domain of an influenza virus hemagglutinin and a naturally occurring GM-CSF molecule.

The difference between the two claims is the recitations "lectin that is capable of binding a carbohydrate and includes the HA carbohydrate binding domain of an influenza virus hemagglutinin" and "carbohydrate binding domain".

However, the lectin that is capable of binding a carbohydrate and includes the HA carbohydrate binding domain of an influenza virus hemagglutinin is the first amino acid sequence which can bind to a carbohydrate is a carbohydrate binding domain, specifically a sialic acid domain

The other difference noted between the two claims is the recitations "ligand for a cell surface polypeptide" and "a naturally occurring GM-CSF molecule".

However, the "a naturally occurring GM-CSF molecule" is encompassed by the generic recitation ""ligand for a cell surface polypeptide".

In the instant, all that is recited in claim 1 of the conflicting patent application is encompassed by claim 1 of the instant patent application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. Claims 1-27 and 67-68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-147 of copending Application No. 10/666885.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a vector comprising a nucleic acid molecule composition encoding a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The difference between the two sets of claims is that claim 1 of the conflicting patent application is directed to a vector construct comprising the nucleic acid sequence encoding the fusion polypeptide recited in claim 1 of the instant patent application.

However, it would have been prima facie obvious for one of ordinary skill in the art to place the vector expression construct in a cell to express fusion polypeptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

26. Claims 1-27 and 67-68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-69 of copending Application No. 10/666898.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a nucleic acid composition encoding a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The difference noted between the two is that claim 1 of the instant patent application is directed at a fusion polypeptide, and claim 1 of the conflicting patent application is directed at a nucleic acid composition that encodes the instantly claimed fusion polypeptide.

However, it would have been prima facie obvious for one of ordinary skill in the art to obtain the coding sequence of the fusion to express/make the fusion polypeptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

27. Claims 1-27 and 67-68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-77 of copending Application No. 10/666834.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide.

The difference between the two claims is that claim 1 of the conflicting patent application requires the presence of an antigen bearing target, whereas claim 1 of the instant patent application does not require the presence of an antigen bearing target. However, claim 1 of the instant patent application is open to the addition of other ingredients, note the transitional language used, "comprising".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

28. Claims 1-27 and 67-68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-77 of copending Application No. 10/667166.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide.

The difference between the two claims is that claim 1 of the conflicting patent application requires the presence of an antigen bearing target, whereas claim 1 of the instant patent application does not require the presence of an antigen bearing target. However, claim 1 of the instant patent application is open to the addition of other ingredients, note the transitional language used, "comprising".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

29. Claims 1-27 and 67-68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-82 of copending Application No. 10/668073.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide.

The difference between the two claims is that claim 1 of the conflicting patent application requires the presence of an antigen bearing target, whereas claim 1 of the instant patent application does not require the presence of an antigen bearing target. However, claim 1 of the instant patent application is open to the addition of other ingredients, note the transitional language used, "comprising".

The other difference noted between the two claims is that the claims in the instant application is directed at a product, and the claims in the conflicting patent

application is directed at a method of using the same product as those provided in the claims in the instant application.

However, because the claims in the conflicting patent application is directed at a method of using a product that is the same as those provided in the claims in the instant application, it is clear that the conflicting patent application has possession of the instantly claimed product. Ergo, because the conflicting patent application has possession of the instantly claimed product, the conflicting patent application anticipates the instantly claimed product.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

30. No claim is allowed.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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